

(19) AUSTRALIAN PATENT OFFICE

(54) Title
Procedure and composition of treatment and/or care of the eye

(51)⁶ International Patent Classification(s)
A61K 9/06 20060101ALI20051
(2006.01) 220BMJP
A61F 9/00 A61K 9/00
(2006.01) 20060101ALI20051
A61F 9/007 008BMJP
(2006.01) A61K 9/08
A61K 9/00 20060101ALI20051
(2006.01) 220BMJP
A61K 9/08 A61K 9/12
(2006.01) 20060101ALI20051
A61K 9/12 220BMJP
(2006.01) A61K 9/20
A61K 9/20 20060101ALI20051
(2006.01) 220BMJP
A61K 31/352 A61K 31/352
(2006.01) 20060101ALI20051
A61K 31/55 220BMJP
(2006.01) A61K 31/55
A61L 12/08 20060101ALI20051
(2006.01) 220BMJP
A61P 37/02 A61L 12/08
(2006.01) 20060101ALI20051
A61P 37/08 008BMJP
(2006.01) A61P 37/02
A61K 9/06 20060101ALI20051
20060101AFI20051 220BMJP
220BMJP A61P 37/08
A61F 9/00 20060101ALI20051
20060101ALI20051 220BMJP
220BMJP PCT/NL02/00012
A61F 9/007

(21) Application No: **2002228449**

(22) Application Date: **2002.01.09**

(87) WIPO No: **WO02/060495**

(30) Priority Data

(31) Number	(32) Date	(33) Country
1017060	2001.01.09	NL

(43) Publication Date : **2002.08.12**

(43) Publication Journal Date : **2003.02.20**

(71) Applicant(s)
Louis Wagenaar

(72) Inventor(s)
Wagenaar, Louis, Johan

(74) Agent/Attorney
Griffith Hack, Level 3 509 St Kilda Road, Melbourne, VIC, 3004

(56) Related Art
SU 1377104
JP 2000247885
RU 205555
DE 2426757

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
8 August 2002 (08.08.2002)

PCT

(10) International Publication Number
WO 02/060495 A1

- (51) International Patent Classification: A61L 12/08,
A61F 9/00, A61K 9/00
- (21) International Application Number: PCT/NL02/00012
- (22) International Filing Date: 9 January 2002 (09.01.2002)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
1017060 9 January 2001 (09.01.2001) NL
- (71) Applicant and
(72) Inventor: WAGENAAR, Louis, Johan [NL/NL]; Joop
den Uyilaan 3, NL-2314 GC Leiden (NL).
- (74) Agent: 'T JONG, Bastiaan, Jacobus; Arnold & Siedsma,
Sweelinckplein 1, NL-2517 GK The Hague (NL).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG,
SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ,
VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR,
GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent
(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR,
NE, SN, TD, TG).
- Published:
— with international search report
— before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments
- For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.



WO 02/060495 A1

(54) Title: PROCEDURE AND COMPOSITION OF TREATMENT AND/OR CARE OF THE EYE

(57) Abstract: The invention provides a procedure for the manufacture of contact lenses for eye treatment, eye protection and eye-care wherein the lenses are impregnated with a suitable composition. The invention also provides a composition for the impregnation of a contact lens for the treatment and/or care and/or protection of the eye, a kit containing such a composition and one or more contact lenses. The invention further provides a method for the treatment and/or care and/or protection of the eye comprising wearing contact lenses impregnated with a suitable composition and a composition for disinfection and/or conservation of eye care products.

**Procedure and Composition of Treatment and/or Care of the
Eye**

5 The current invention relates to the use of
dexpantenol as a constituent of a contact lens care
composition, a composition for the impregnation of a
contact lens for the treatment and/or care and/or
protection of the eye, a kit containing such a composition
and one or more contact lenses as well as contact lenses
10 impregnated with the composition.

Because they regularly have unusual objects in
their eyes for years contact lens wearers have a higher
chance of damaging their cornea, eye-stratum, the
endothelium or other parts of the eyes than non-wearers,
15 for example because chemical substances which (may) cause
irritation or damage to the eye could be released from the
lens or the surface of the lens after inserting the lens
into the eyes. Lenses which have not been properly cleaned
or damaged lenses as well as dust-particles, traces of
20 sand or pollen which have gotten under the lens could also
affect the cornea. These damages or irritations can be
superficial and temporary, but could also result in far-
reaching consequences since lenses are usually worn daily.
Health risks could occur, varying from irritated and red
25 eyes to serious complications such as permanent damage of
the cornea resulting in blindness.

The cause of such complications is multifarious.
Placing the contact lens onto the eye disturbs its
physiological condition. After habituation a new balance
30 will be reached that can be disturbed again by various
factors, such as ageing of the contact lens, damage to and
deposit on the lens, change of tear-flow with respect to
composition and quantity due to frequency and manner of
winking, chemical toxicity of substances the user is in
35 contact with, mechanical pressure and chronic lack of
oxygen. The ageing of the user may bring about changes in
his or her eyes thereby disturbing the physiological

balance. The use of medication or the development of allergies may also lead to irritations or damage of (parts of) the eyes.

Because nowadays contact lenses are frequently
 5 used for longer periods of time careful and regular
 cleaning has become more important. If this is not done
 sufficiently for instance bacteria, proteins etc. may
 cause irritations and damage (more promptly). To prevent
 permanent damage it is vital that possible damage to the
 10 cornea or other parts of the eyes is treated as soon as
 possible.

Moreover, contact lens wearers may need to extra
 protect their eyes. It could be useful to the eyes to
 dispose of extra nutrition, such as vitamins and pro-
 15 vitamins or (also) those substances which offer protection
 or allow, support or accelerate the repair of an occurring
 damage. In eye healthcare several products are known to
 assist in the (accelerated) recovery of the soundness of
 the cornea. These products, however, usually have to be
 20 administered (dripped in or applied onto the eye)
 separately or have to be swallowed by the user.

It is the aim of the current invention to provide
 the opportunity for a long-term care or treatment and/or
 protection and/or care of the eyes.

25 Considering the possibilities of irritation and
 damage to the cornea, the stratum, the endothelium or
 other parts of the eyes are manifold, one requires
 protection, conditioning and, whenever possible,
 restoration of the sustained damage to the eye. The
 30 current invention therefore relates to the use of
 dexpanthenol as a constituent of a contact lens care
 composition comprising the impregnation of contact lenses
 in a solution which contains dexpanthenol for the care
 and/or protection of the eyes. By wearing contact lenses
 35 the dexpanthenol will be in contact with (part of) the
 eyes. This way the lens will be a method of administering
 the dexpanthenol which will often imply a more long-

lasting administering compared to current eye-drops. The dexpantenol can be either absorbed into the lens material or be attached to them or both. The term 'impregnate' in this application refers to either of these or to a combination of both.

The invention further provides the use of dexpantenol:

- (a) in the treatment or prevention of dry eyes in a contact lens solution;
 - (b) in the treatment or prevention of allergic symptoms of the eye;
 - (c) in a contact lens solution;
 - (d) in the protection of the eye in a contact lens solution; and
 - (e) in the treatment of or prevention of eye-diseases, in a contact lens solution;
- and in the increase of wearing comfort of contact lenses.

Furthermore the current invention provides a composition for the impregnation of contact lenses for the care and/or protection of the eyes, comprising dexpantenol.

It further provides a lens care composition comprising dexpantenol.

For the benefit of the user dexpantenol can be combined with the compounds usually used for disinfecting, cleaning, insertion, moisturizing, rinsing or storing of contact lenses, so that the user need not add these compounds separately. However, it is likewise possible to just impregnate the lenses with the dexpantenol to prevent damage caused by (other) cleaning-agents or disinfectants.

Products used for maintenance and storage of contact lenses, like cleaning products and disinfecting solutions, and sprays, so-called all-in-one solutions, storage liquids and rinsing liquids, insertion solutions and moisturizers, neutralizers in either liquid or tablet form, gels, coatings and tablets which either make or

assist in making contact lens solutions or make solutions come into being or are used for or in such solutions.

According to the current invention the composition can therefore appear in various forms, such as
5 a solution, spray or tablet which after dissolution makes a solution. Compounds intended for the care of contact lenses may also be part of a tablet which is combined with a solution that contains the care, treatment or protection agent or the reverse. Obviously both could also be
10 included in one tablet or in separate tablets. Even so compounds can be included in a solution that is (to be) mixed with a solution without a compound.

Since the current substances which necessarily have to be applied for their germicidal and preservative
15 effects in eye-care solutions, eye-drops and contact lens care solutions and which are germicidal in a short period of time and sufficiently limiting increase in germ population usually have the disadvantage of causing irritation or even attacking the eye to a large or lesser
20 degree it would be greatly advantageous to use dexpanthenol in eye-care solutions, eye-drops and contact lens solutions for germicidal or conservation purposes which are non-irritant or protect against these irritations or damages. Possible damage and irrigation of
25 the cornea or other parts of the eye will thus be avoided.

The composition according to the current invention can be applied when impregnating all kinds of contact lenses, especially and preferably soft lenses, but
30 also hard lenses, disposable lenses and long-lasting ones as well as extended wear lenses and intra-ocular lenses would benefit. Impregnation can be carried out by the user, for instance during maintenance, but also, as with new lenses, in the delivery packaging.

It is not necessary for the user using the
35 contact lenses according to the current invention to be already familiar with wearing lenses. People, and even animals, who in fact do not need any eye-correction, but

who require for instance certain nutrients for the eye or products to (possibly) set off, support or accelerate healing sores or injuries could wear contact lenses or similar objects according to the current invention on or
5 in the eye to facilitate the required compound(s) on or into the eye. It is not necessary for the active component with which contact lenses have been impregnated to repair or prevent any damage.

Applications of contact lenses according to the
10 current invention could be found in the treatment of so-called 'dry eyes' or irritated or red eyes, hence called 'dry eyes'. Currently mainly eye-drops are used to treat this. Such eye-drops, however, usually offer only short-term relief. In order to lengthen the availability of the
15 active agents for the treatment of the eyes several complex or expensive possibilities for slow-release eye-drops have been proposed. The contact lenses according to the current invention offer a simple, cheap and elegant alternative.

20 It could be particularly advantageous to use the dexpanthenol suggested in the current invention as giving relief to dry eyes in combination with polymers from which is known or believed that they, when used in eye-drops, offer relief, such as polymers of the type PVP, PVA, HPMC,
25 HPC, Carbomere or Dextrane.

Moreover, the use of contact lenses according to the current invention, will generally result in a more constant level of the effective agent at the point of application than would have been possible with the use of
30 eye-drops or even eye balm. Eye-balm also has the disadvantages of causing limited eyesight directly after application and a less easy way of application for some users compared to applying contact lenses. For wearers of contact lenses the use of the current invention with their
35 own lenses is particularly economical, because they do not need to perform any supplementary actions.

An advantage of the current invention is that the

price of contact lenses has dropped considerably over the last few years especially that of short-term use lenses such as the so-called day-lenses, week-lenses, month-lenses or three-months'-lenses. Such lenses are a preferable embodiment of the current invention.

The current invention will be illustrated in the following examples:

EXAMPLES

Examples of compositions to be used in the procedure according to the current invention are the following:

A. All-in-one solutions:

1. PHMB HCl 2.5 ppm
2. Boric Acid 0.75%
3. Borax 0.15%
4. NaCl 0.40%
5. EDTA-Na 0.03%
6. HPMC 10,000 0.10%
7. Dexpanthenol 1.0%
8. pH adaptation with NaOH or HCL ad pH 7.4

In the claims which follow and in the preceding description of the invention, except where the context requires otherwise due to express language or necessary implication, the word "comprise" or variations such as "comprises" or "comprising" is used in an inclusive sense, i.e. to specify the presence of the stated features but not to preclude the presence or addition of further features in various embodiments of the invention.

20022228449 23 Nov 2007

- 7 -

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. Use of dexpanthenol as a constituent of a contact lens care composition.
- 5 2. Use according to claim 1, wherein the contact lens care composition comprises one or more constituents selected from the group consisting of polyvinyl propylene (PVP), polyvinyl alcohol (PVA), hydroxyl propyl cellulose (HPMC), hydroxyl propyl methyl cellulose (HPC), Carbomere, and Dextrane.
- 10 3. Use according to claim 2, wherein the contact lens care composition comprises dexpanthenol and HPC.
- 15 4. Use according to claim 2, wherein the contact lens care composition comprises dexpanthenol and HPMC.
- 20 5. Use according to any of the claims 1-4, wherein the contact lens care composition comprises one or more further constituents selected from the group consisting of buffer substances, substances that affect the tonicity, surface-active substances, substances that affect viscosity, complexing agents, moisturizing agents, and antimicrobial compounds.
- 25 6. Use according to claim 5, wherein the contact lens care composition comprises dexpanthenol, HPMC, NaCl, and EDTA-Na.
- 30 7. Use according to claim 6, wherein the contact lens care composition comprises
 - polyhexamethylene biguanide (PHMB) HCl 0.5-5 ppm
 - 35 - Boric acid 0-1%
 - Borax 0-0.3%
 - NaCl 0.09-0.9%

N:\Melbourne\Cases\Ftnt\50000-50999\50006.ADJSpecie\Claims.doc 23/11/07

2002228449 23 Nov 2007

- 8 -

- ethylene diamine tetracetic acid (EDTA)-Na
0.01-0.1%
- HPMC 10,000 0.1-0.30%
- Dexpanthenol 0.1-5%.

5

8. Use according to any of the claims 1-7, wherein the contact lens care composition takes the form of a spray, solution, gel, coating and/or tablet.

10

9. Use according to any of the claims 1-8, wherein the use comprises the storage of a contact lens in the contact lens care composition.

15

10. Use according to any of the claims 1-9, wherein the contact lens care composition is a day-lens contact lens care composition.

20

11. Use according to claim 10, wherein the use comprises the storage of a day-lens contact lens in the contact lens care composition.

25

12. Use of dexpanthenol for the preparation of a contact lens care composition for the treatment of the eye.

30

13. Use according to claim 12, wherein the treatment is the treatment of dry and/or irritated eyes during contact lens wear.

35

14. Use of dexpanthenol in the treatment or prevention of dry eyes in a contact lens solution.

15. Use of dexpanthenol in a contact lens solution.

40

16. Use of dexpanthenol in the protection of the eye in a contact lens solution.

N:\Melbourne\Cases\Patent\50000-50999\50006.AU\Specie\Claims.doc 23/11/07

20022228449 23 Nov 2007

- 9 -

17. Use of dexpanthenol in the treatment of or prevention of eye-diseases, in a contact lens solution.

18. Use of dexpanthenol in the increase of wearing
5 comfort of contact lenses.

19. A contact lens care composition comprising

- PHMB HCl 0.5-5 ppm
- Boric acid 0-1%
- 10 - Borax 0-0.3%
- NaCl 0.09-0.9%
- EDTA-Na 0.01-0.1%
- HPMC 10,000 0.1-0.30%
- Dexpanthenol 0.1-5%.

15

20. A contact lens care composition comprising

- PHMB HCl 0.5-5 ppm
- NaCl 0.09-0.9%
- EDTA-Na 0.01-0.1%
- 20 - HPMC 10,000 0.1-0.30%
- Dexpanthenol 0.1-5%.
- Buffer 0-1.3%

21. Uses of dexpanthenol or contact lens care
25 compositions containing dexpanthenol substantially as herein described with reference to the examples.

H:\Melbourne\Cases\Patent\50000-50999\506005.AU\specie\Claims.doc 23/11/07